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In re Application of:

FELD ET AL.

Serial No.: 09/691,889

Filed: October 20, 2000

**For: NUCLEIC ACID CONSTRUCTS
AND CELLS ...**

Examiner: Anne-Marie Baker

Commissioner of Patents and Trademarks
Washington, D.C. 20231

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MAR 06 2003

**TECH CENTER 1600/2900**

Group Art Unit: 1632

Attorney  
Docket: 00/20989

## DECLARATION OF YAIR FELD UNDER 37 CFR 1.132

I am presently employed as a post-doctoral fellow at the Technion, Department of physiology. I received my Ph.D. degree from the Technion in physiology.

My research focuses on gene therapy for cardiac arrhythmias. Since the beginning of my career, I have published 2 scientific articles in highly regarded journals, and have presented my achievements at many international scientific conferences.

I am a co-inventor of the subject matter claimed in the above-referenced U.S. patent application.

I have read the Official actions issued with respect to the above-identified application.

In this Official action, the Examiner has rejected claims 23-37 under 35 U.S.C. § 112 first paragraph because the specification does not assert any use,

other than treatment, for the claimed method of cellular implantation and the teachings of the specification are limited to analysis of conduction properties of cells in culture. Furthermore, in the absence of working examples or guidance, Examiner has rejected claims 23-37 because methods of cellular transplantation and/or gene therapy are unpredictable.

The Appendix section enclosed herewith, which presents recent results obtained in our lab, illustrates that genetically modified fibroblasts over-expressing the Kv1.3 ion channel are capable of modifying the electrophysiological properties of myocardial cells in vitro and in-vivo.

These results conclusively demonstrate that the methodology described and claimed in the instant application can be utilized to make and use the methodology of the present invention to modify the electrophysiological properties of cells and tissues, thereby providing evidence that the rejections of claims 13-20 under 35 U.S.C. § 112 first paragraph are unfounded.



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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

23 February 2003

Dr. Yair Feld

Dept. Physiology

Technion-Israel Institute for Technology. Haifa, Israel

*Enc.:*

CV of Yair Feld and Appendix

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**TECH CENTER 1600/2900****Curriculum Vita - Yair Feld**

Date of birth: 6.12.71

Place of birth: Israel

Marital status: Married + 1.

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**Education:**

1992-1995 - B.Sc. in Physics with honors at the University of Tel-Aviv, faculty of physics and astronomy.

1998 - 2000 - M.Sc. in Medical sciences at the Technion - Israel institute of technology.

1995 - 2003 - M.D. at the Technion - Israel institute of technology.

2000 - 2003 - Ph.D. at the Technion - Israel institute of technology. School of medicine, Physiology.

**Military service:**

1990-1993 - Rank: First sergeant. Position: Officer of manpower. Unit: Infantry.

**Current position:**

2002- Post doctoral - Technion - Israel institute of technology.

2002 - Member of the board of directors - Relaxis Ltd.

**Previous positions:**

1994 - 1995 - Non-frontal tutor at the University of Tel-Aviv Faculty of physics.

1996 - 1998 - Physicist in an electro-optics company.

1998 – 2002 - tutor at the Technion faculty of medicine, physiology department.

1995 - 2002 - coach of the Technion's squash team.

#### **Publications:**

1. Electrophysiological Modulation of Cardiomyocytic Tissue by Transfected Fibroblasts Expressing Potassium Channels: A Novel Strategy to Manipulate Excitability. **Yair Feld**, Meira Melamed-Frank, Izhak Kehat, Dror Tal, Shimon Marom, Lior Gepstein. *Circulation*. 2002 Jan;105:522-529.
2. Evolution of action potential propagation and repolarization in cultured neonatal rat ventricular myocytes. Gideon Meiry, Yotam Reisner, **Yair Feld**, Stanislav Goldberg, Michael Rosen, Noam Ziv and Ofer Binah. *J Cardiovasc Electrophysiol*. 2001 Nov;12(11):1269-1277.

#### **Active Grant Supports:**

##### **Co-Investigator**

Modification of excitable tissues by genetically engineered cellular grafts.

State of Israel – Chief scientist office – Nofar program  
\$100,000

##### **Principal-Investigator**

Genetically engineered cell grafts transfected with ionic channels: A novel cell therapy strategy for treatment of abnormalities in excitable tissues.

Mitchel foundation  
\$25,000

#### **Awards:**

3.4.2001 – J.J. Kellerman young investigators award – first place on behalf of the Israel Cardiology Association.

### Conferences:

1. North American Society of Pacing and Electrophysiology. Assessment of hybrid cardiomyocytic cultures with fibroblasts transfected with potassium channel Kv1.3: A novel approach for gene therapy. **Yair Feld**, Meira Melamed Frank, Leonid Heimovitz, Shimon Marom, Lior Gepstein. 2001.
2. American heart association. Long Term, High-Resolution, Electrophysiological Assessment of Human Embryonic Stem Cell Derived Cardiomyocytes: A Novel in Vitro Model for the Human Heart. Izhak Kehat, Dorit Karsenti, Michal Amit, Mirit Drukman, **Yair Feld**, Joseph Itskovitz-Eldor, Lior Gepstein. 2000.
3. International Society for Heart Research. Evolution of action potential propagation and repolarization in cultured neonatal rat ventricular myocytes. Meiry G, Reisner Y, **Feld Y**, Goldberg S, Rosen M, Ziv N, and Binah O. 2001.
4. International Society for Heart Research. Assessment of hybrid cardiomyocytic cultures with fibroblasts transfected with potassium channel Kv1.3: A novel approach for gene therapy. **Yair Feld**, Meira Melamed Frank, Leonid Heimovitz, Shimon Marom, Lior Gepstein. 2001.
5. North American Society of Pacing and Electrophysiology. Evolution of action potential propagation and repolarization in cultured neonatal rat ventricular myocytes. Binah O, Meiry G, Reisner Y, **Feld Y**, Goldberg S, Ziv N, and Rosen M. 2001.
6. Israel Heart Society. Assessment of hybrid cardiomyocytic cultures with fibroblasts transfected with potassium channel Kv1.3: A novel approach for gene therapy. **Yair Feld**, Meira Melamed Frank, Leonid Heimovitz, Shimon Marom, Lior Gepstein. 2001.
7. International Society for Heart Research. A novel in-vitro model for slow conduction in the human heart: High-Resolution, electrophysiological assessment of human embryonic stem cell derived cardiomyocytes. Kehat I, Druckmann M, Gepstein A, **Yair Feld**, Amit M, Karsenti D, Itskovitz-

Eldor J and Lior Gepstein. 2001.

**General:**

Active member of the Israeli squash national team.